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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,361	07/26/2001	George M. Grass	109904-00015	6311

7590 07/28/2006

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EXAMINER	
BRUSCA, JOHN S	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,361	GRASS ET AL.	
	Examiner	Art Unit	
	John S. Brusca	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52,80-121 and 137-231* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-52,80-121 and 137-231* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 June 2006 has been entered.

Priority

2. The claim for priority has been perfected in view of the amendment to the specification filed 30 June 2006.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-53, 80-121, and 137-231 rejected under 35 U.S.C. 103(a) as being unpatentable over Grass (reference BW in the Information Disclosure Statement filed 17 July 2001) in view of Gex-Fabry et al. (reference BT in the Information Disclosure Statement filed 17 July 2001).

The claims are drawn to a method of using a pharmacokinetic model to predict a pharmacokinetic property of a compound in a second anatomical location by use of a pharmacokinetic property of a test compound in a first anatomical location. In some embodiments parameters such as a selected adjustment parameter or a regional correlation parameter are refined by use of data from a plurality of compounds. In some embodiments the claims are drawn to computers or programs that execute the method. In some embodiments the model uses in vitro data, log functions, programs and computers using if..then statements, models comprising absorption models in the gastrointestinal tract, differential equations, and models that comprise properties of two different species of animal or tissues or cells.

Grass et al. shows in the abstract and throughout pharmacokinetic models that predict behavior of compounds in animals. Grass shows use of in vivo, in situ, and in vitro pharmacokinetic data of compounds on pages 202-205, models with log functions on page 205, computers and programs that execute the method on page 207, programs with if..then statements on page 207. models of absorption in multiple segments of the gastrointestinal tract on page 207 and throughout, models using differential equations on page 208, models that compare behavior

of different species of animals on pages 209-211, and models that use behavior of tissue and in vitro cells on page 209-211. Grass shows in figures 19 and 20 that the models provide accurate predictions of absorption of two different compounds in the gastrointestinal tract. Grass et al. does not explicitly show fitting of pharmacokinetic data of multiple compounds to derive parameters for use in the model.

Gex-Fabry et al. reviews computer models of pharmacokinetic behavior of compounds in anatomical sites. Gex-Fabry et al. shows on page 513 and beyond the use of data to refine parameter values that are used in computer pharmacokinetic models.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method and computer models of Grass et al. by refining the parameters used in the model by use of data from a plurality of compounds because Gex-Fabry et al. shows such refinement is useful to obtain more accurate parameters.

Response to Arguments

6. Applicant's arguments filed 30 June 2006 have been fully considered but they are not persuasive. The applicants state that neither Grass et al. nor Gex-Fabry et al. show methods that use selected adjustment parameters or regional correlation parameters. Selected adjustment parameters as discussed on pages 21-22 of the specification allow for correction of in vitro to in vivo pharmacokinetic behavior, or for correction of animal species differences in pharmacokinetic behavior. Regional correlation parameters as discussed on page 22 of the specification allow for correction of anatomical site differences in pharmacokinetic behavior. However while Grass et al. does not explicitly discuss methods using equivalents of selected

adjustment parameters or regional correlation parameters, the model of Grass et al. makes corrections for in vitro to in vivo pharmacokinetic behavior, and for anatomical site differences. Grass et al. shows computer models that predict pharmacokinetic data of a test compound in multiple locations in the gastrointestinal tract (see results presented in pages 211-216). Grass et al. shows that the model may be based on data of multiple compounds in the gastrointestinal tract of different animals and tissue culture (see pages 209-211). The applicants state that Gex-Fabry et al. does not teach the use of multiple compounds, however Grass et al. does. Gex-Fabry et al. was cited to show the obviousness of refining parameter values in the context of modeling pharmacokinetic behavior of compounds.

Conclusion

7. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

J. S. Brusca 19 July 2006

John S. Brusca

Primary Examiner